In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1535V Filed: June 28, 2018 Not to be Published.

SAMANTHA RIVERA, as Mother and
Natural Guardian, and TIMUR RIVERA,
as Father and Natural Guardian, of S.R.,
**

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Petitioners,

Influenza ("flu") vaccine;

V. **

Guillain-Barré syndrome ("GBS"); chronic inflammatory demyelinating polyneuropathy ("CIDP"); no expert;

SECRETARY OF HEALTH AND HUMAN SERVICES,

notice to withdraw petition

Respondent.

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<u>Jeffrey S. Pop</u>, Beverly Hills, CA, for petitioners. <u>Daniel A. Principato</u>, Washington, DC, for respondent.

MILLMAN, Special Master

ORDER CONCLUDING PROCEEDINGS¹

On October 16, 2017, petitioners filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that trivalent influenza ("flu") vaccine their daughter S.R. received on October 20, 2014 when she was eight and one-half months old caused her a Table Guillain-Barré syndrome ("GBS") or, in the alternative, a non-Table GBS, and chronic inflammatory demyelinating polyneuropathy ("CIDP"). Pet. at Preamble and ¶ 68. Petitioners allege that the onset of S.R.'s symptoms was November 7, 2014. Id. at ¶ 7.

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

Onset of Neurologic Disease

Although petitioners allege that S.R. was perfectly normal before her October 20, 2014 flu vaccination, the medical records show numerous histories from S.R.'s mother or both parents that S.R. was not normal for months before the flu vaccination.

On November 18, 2014, S.R.'s parents brought her to the Emergency Department ("ED") of New York Methodist Hospital. Med. recs. Ex. 10, at 210. They told Dr. Zainab Qayumi that S.R.'s mother noticed that, when S.R. was six months old (August 2014), she was unable to bear weight on her legs or stand in a bouncy chair. <u>Id.</u> Dr. Christopher Kelly on the same date wrote that S.R.'s lower extremities had never had good tone. Id. at 213.

During S.R.'s hospitalization at New York Methodist Hospital from November 18-25, 2014, S.R.'s mother gave a history that when S.R. was about six months of age (about August 2014), her parents bought her a bouncer and noticed that S.R. was not able to keep her legs straight when she bounced. Med. recs. Ex. 6, at 25. Instead, her legs would go sideways. <u>Id.</u> On November 21, 2014, Dr. Simona V. Proteasa, a pediatric neurologist, wrote that S.R. likely had an insidious onset of weakness from six months of age (August 2014) initially in her lower extremities slowly progressing to her upper extremities. Med. recs. Ex. 11, at 8. On November 23, 2014, S.R.'s mother told Dr. Amr Eimeki that she first noticed decreased movement of S.R.'s lower extremities in July 2014. Med. recs. Ex. 10, at 221.

On December 18, 2014, in a pediatric neurology follow up consult, Dr. Proteasa wrote that S.R.'s symptoms started four to five months earlier (July to August 2014) when her parents noticed S.R. was weaker in her lower extremities and, according to them, she was unable to push with her lower extremities when they placed her in a jumping chair. Med. recs. Ex. 6, at 43.

On December 24, 2014, Dr. Proteasa wrote that S.R.'s parents noticed about five months earlier (May 2014) that S.R.'s toes on both feet were curled downward. <u>Id.</u> at 47. They also noticed that S.R.'s legs were weaker than her arms. Id.

The history at least four doctors recorded that the parents and/or S.R.'s mother gave was that S.R's weakness in her lower extremities began months before she received flu vaccine. In addition, S.R. has never had good tone in her lower extremities. If these pre-vaccination signs and symptoms indicate onset of a neurologic disease before flu vaccination, then: (1) petitioners cannot prevail on a claim of a Table GBS because the Vaccine Injury Table requires onset between 3-42 days after flu vaccination (42 C.F.R. §100.3(a)(XIV)(D)); and (2) petitioners' sole claim can only be significant aggravation, which the Vaccine Act defines as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health" (42 U.S.C. § 300aa-33(4)).

What neurologic disease does S.R. have

Although doctors initially diagnosed S.R. with GBS, her course and variation in

symptoms caused a number of physicians to question this diagnosis. The insidious onset is not typical of GBS. The dramatic worsening over many months with the addition of more symptoms of difficulty breathing, not eating, and failure to thrive is not typical of CIDP.

The absence of elevated protein in her cerebrospinal fluid on a repeat lumbar puncture ("LP") on December 18, 2014 which showed a high white blood cell ("wbc") count of 25, but normal protein, is not typical of either GBS or CIDP (her initial LP was traumatic with a wbc of 1800 and a slightly elevated protein of 51). Her head circumference measured at the 2nd percentile on November 10, 2014 when her head circumference at birth was measured at the 25th percentile is not typical of either GBS or CIDP. Doctors have theorized she has a genetic illness, but they have not identified which one.

If S.R. has chronic relapsing CIDP which began months before S.R.'s flu vaccination, did flu vaccination change the course of this disease or is the course that S.R. has had typical of chronic relapsing CIDP?

Does S.R. have Charcot-Marie-Tooth Disease Type 1 ("CMT1"), which typically presents with weakness in the feet and ankles? CMT1 includes pes cavus foot deformity and hip dysplasia.

Does S.R. have chronic relapsing CIDP superimposed on CMT1?

The undersigned gave petitioners the option to amend their petition to allege significant aggravation. In a status report petitioners filed on June 8, 2018, petitioners state that they are considering dismissing their case. On June 13, 2018, the undersigned issued a Formal Notice to petitioners that they could remain in the Vaccine Program or withdraw their petition.

On June 27, 2018, petitioners filed a Notice of Withdrawal of the Petition.

The undersigned **ORDERS** petitioners' petition withdrawn and **ORDERS** the Clerk of Court to conclude proceedings.

DISCUSSION

To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was

the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" <u>i.e.</u>, "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." <u>Grant</u>, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. <u>Id.</u> at 1148.

Petitioners must show not only that but for flu vaccine, S.R. would not have had GBS or CIDP, but also that flu vaccine was a substantial factor in causing S.R.'s GBS or CIDP. <u>Shyface</u> v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioners based solely on their allegations unsubstantiated by medical records or medical opinion. The medical records do not support petitioners' allegation.

The Federal Circuit in <u>Capizzano v. Sec'y of HHS</u>, 440 F.3d 1317, 1326 (Fed. Cir. 2006), emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." <u>See also Broekelschen v. Sec'y of HHS</u>, 618 F.3d 1339, 1347 (Fed. Cir. 2010); <u>Andreu v. Sec'y of HHS</u>, 569 F.3d 1367, 1375 (Fed. Cir. 2009). None of petitioner's treating physicians supports petitioners' allegation that flu vaccine caused S.R.'s neuropathy.

Petitioners have not filed a medical expert opinion in support of their allegations.

Petitioners filed a Notice of Withdrawal of the Petition.

The undersigned **GRANTS** petitioners' motion under Vaccine Rule 42 U.S.C. § 300aa-21(a) to withdraw their petition, and **ORDERS** the Clerk of Court to conclude proceedings.

CONCLUSION

The petition is **ORDERED** withdrawn and the Clerk of Court is **ORDERED** to conclude proceedings under Vaccine Rule 21(a)(3).

IT IS SO ORDERED.

Dated: June 28, 2018

/s/ Laura D. Millman

Laura D. Millman

Special Master